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ABSTRACT

To illustrate the types of factors that must be considered in evaluating public documents, this paper analyzes a number of possible outcomes resulting from one type of document, the patient package insert (PPI) designed to provide consumers of prescription drugs with information about the drugs. It first outlines the intended sequence for a PPI: (1) the patient receives the PPI, reads and comprehends it, (2) is satisfied with the prescribed treatment, (3) follows the prescribed regimen, and (4) improves in health. It then diagrams and discusses possible variations in the intended sequence that might result from such factors as the patient's failure to read the PPI, the patient's lack of comprehension of the PPI, or the patient's decision against taking the prescribed drug. It also shows possible variations in physician behavior that might affect the PPI sequence and considers complications such as those that might arise from a PPI's presentation of information that frightens a patient. In its conclusion, the paper notes the usefulness of such analyses in document evaluation, outlines implications of the PPI analysis, and asserts that an evaluation should be a historical undertaking rather than a one-shot study. (GT)

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Technical Report No. 2

Evaluating Documents: The Case of Patient Package Inserts

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EVALUATING DOCUMENTS:
The Case of Patient Package Inserts
Robert E. Krug, Ph.D.

Evaluation remains fashionable despite a decade of disappointment with its visible products. Rightly or wrongly, the dismal finding of "no difference" has been blamed, not on the evaluator or the evaluation procedures, but on the programs being evaluated. So evaluation services remain in demand.

Language simplification in public documents has become fashionable more recently, but the word is clearly out. There are state laws, Presidential directives, and agency executive orders which mandate that documents prepared for public use must be comprehensible to the public who will use them. Some of the orders include a criterion--such as a certain score on a readability measure--while others do not. The inclusion of a criterion may simplify enforcement proceedings which rest on compliance with the letter of the law. But no one appears to believe that meeting the criterion of a readability score assures compliance with the broader spirit of the language simplification movement. Hence, there is growing demand for "evaluations" of new, and, hopefully, improved documents.

In this paper I would like to examine, in a real-world context, some of the possible meanings of the verb "evaluate" when applied to public documents. The context is important because documents are embedded in complex systems which involve a variety of individual and institutional actors, other documents, potential constraints, sanctions, and rewards, and all of those other "messy variables" which jointly constitute the real world. Not everything which happens in such a system is attributable to a document, a trite truth often ignored by the person or agency whose present focus the particular document happens to be.

In my examination, a particular class of document will be used extensively for illustrative purposes. This class, here termed the Patient Package Insert, or PPI, is designed to provide the consumer of prescription drugs with information about the drug. The information is to be delivered at the point of purchase. PPIs have been required for oral contraceptives and estrogen products for some time; the Food and Drug Administration has made known its intention to require PPIs for a broad range of prescription drugs and to ultimately include most drugs under this labeling requirement. Public hearings have been held, a national conference was sponsored, research contracts have been let, an Institute of Medicine/National Academy of Science report on research needs was published in August 1979, and FDA's provisional rule was published in the Federal Register in July 1979. In some form, for some number of drugs, PPIs will soon become common elements in the physician to pharmacist to patient sequence which is used to dispense prescription drugs.

PPIs will doubtless vary in length, intrinsic complexity, format and completeness. But in all cases, PPIs will include information concerning (a) indications--the conditions for which the drug is intended, (b) contraindications--conditions or circumstances under which the drug should not be used or things which should not be done by a person taking the drug, (c) expected and possible side effects, (d) dosage options and restrictions, and (e) what to do if...occurs. For more complete information on the content and format proposed for the PPI, the provisional (or final) FDA rule is recommended reading. The rule also includes a list of drugs for which PPIs are being considered.

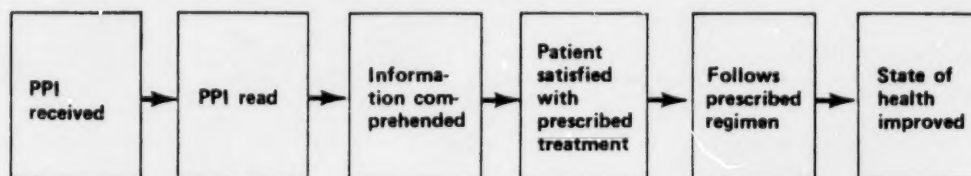
I have been privileged to be a member of the IOM/NAS Committee on PPI research needs. Some of the material to be presented was prepared initially for the Committee's consideration. But nothing presented here is to be construed as the position or viewpoint of the Institute of Medicine, the

National Academy of Science, or the Food and Drug Administration. The paper is not primarily about the PPI; it is about some options to be considered if one wanted to evaluate a document. The PPI analysis is a case study.

The approach taken is simple-minded and direct. The first step is to lay out what AIR calls the program rationale, and what others have called the program logic, or the program flow chart, or whatever. It is convenient to think of this, whatever we call it, as the intended sequence. Figure 1 presents the intended sequence for a PPI--what is supposed to happen--in terms of the patient.

Figure 1

PATIENT RATIONALE - INTENDED SEQUENCE



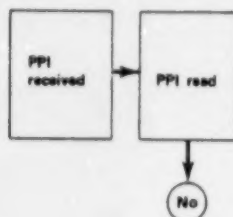
The figure represents the PPI version of utopia. We now want to examine, for each of the elements in the sequence, equally plausible alternative outcomes--the complications which interfere with the attainment of the utopian condition. The first of these, that the PPI is not received, we will ignore on the grounds that the problem, if it arises at all, will be resolved. The sequence to be examined assumes that a PPI is delivered along with the prescribed drug.* The first complication is shown in Figure 2 on the next page; the PPI is received but not read. Readership of the PPI for oral contraceptives is very high (85 to 95%) in the surveys reported;

* Precisely how and when the PPI is delivered is of great importance. It appears probable that the consumer will get the PPI and the drug simultaneously and will pay for the prescription prior to reading the PPI. More "rational" schemes have been judged to be impractical.

Figure 2

1.

PATIENT RATIONALES - COMPLICATIONS



but the population which uses oral contraceptives is not representative of the total population using prescription drugs. So readership will certainly be "evaluated" for a population which may be segmented by age, sex, ethnic group membership, education, language group, and other variables believed to influence the behavior of reading. The results of such evaluations may well have implications for document design, and it may be possible to increase readership for some population segments by altering the PPI--its language, length, format, etc. Two points merit attention.

First, in assessing any subsequent element in the sequence--compliance with the prescribed drug regimen, for example--an attribution to the PPI requires, as a necessary but not sufficient condition, that the PPI was actually read. This simple and obvious fact can increase the cost and complexity of any evaluation of PPI effects; if non-readership is common, results obtained from randomly chosen cross-sectional samples will be interpretable only if readership or non-readership is established for each subject. This will often be difficult.

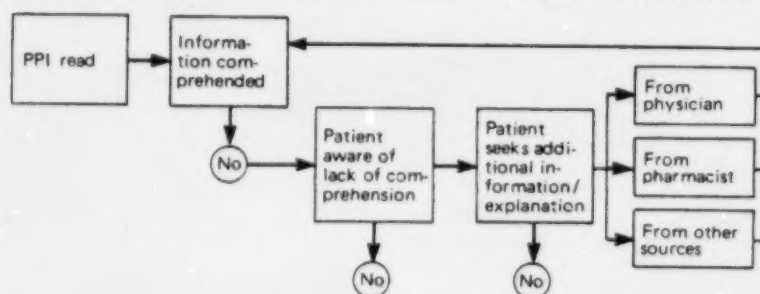
Second, readership is not exclusively a document problem and may not be amenable to significant influence through manipulating document design variables. Our society abounds in widely-unread documents: warranties, loan agreements, insurance policies come to mind. For each of these classes, simplified versions exist which are demonstrably more comprehensible than the versions they replaced. But there is no evidence of which I am aware that voluntary readership has increased; in general,

people continue to not read warranties, loan agreements, or insurance policies. And the extent to which the document per se can alter this may be extremely limited.

We proceed to the next element in the sequence, remembering that we do so only for that portion of the population which reads the PPI. Figure 3 illustrates some of the plausible outcomes. The first alternative, the PPI is read but not understood,

Figure 3

2.



is clearly a legitimate problem for the document designer. And a reasonably adequate technology exists which can produce documents, including PPIs, which will be comprehended by the audience toward which the document is directed. But the PPI, in common with many documents, has multiple audiences, and it is not certain that multiple versions of a particular PPI will be tolerated by the PPI-dispensing system. Further, the FDA mandate for both completeness and simplified language may lead to some rather lengthy PPIs which will discourage readership and/or lead to reduced levels of comprehension through scanning rather than reading.* In general, however, comprehensibility is a fair criterion for use in evaluating PPIs, and one which will certainly be employed.

However well the PPI is prepared, we will have some cases

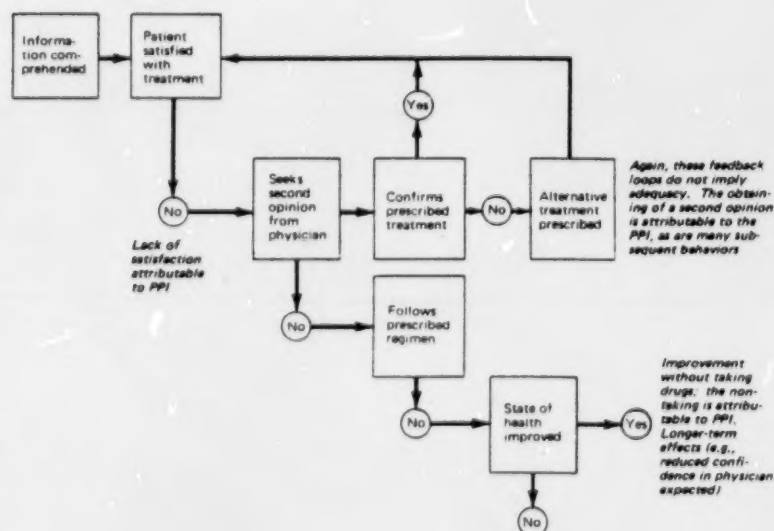
* It should be noted that what the patient "needs to know" is to some extent idiosyncratic, and this fact argues for completeness rather than for abridged lists of high priority information.

where the information is not understood. This leads to the two possibilities shown: the patient does or does not recognize the failure to comprehend. If the failure is not recognized, the attribution of subsequent events as PPI effects will again be clouded; the subsequent behavior will derive in part from a misunderstanding. Unless the misunderstanding is identified by the evaluator, the more ultimate outcomes will be misinterpreted.

If the failure to understand is recognized by the patient, some "interesting" PPI effects may occur. Tracking these effects should be the most important part of a complete evaluation, but one that lies beyond any narrow definition of document evaluation and focuses instead on the system in which the document is embedded. And to repeat, all important documents are embedded in such systems. The feedback loop in Figure 3 does not imply that the additional information gained is adequate on the first or any other traverse. The process can be iterative and all exits are permitted.

To conserve space in the presentation, Figures 4, 5, and 6 are presented with annotations which comment on the issues of attribution to PPI, evaluation design requirements, and some possible longer term consequences.

Figure 4



In Figure 4, one chain of outcomes is concerned with the patient's decision to not take the prescribed drug, with the non-compliance potentially attributable to the PPI. If the patient's health improves, many would conclude that the PPI - effect was beneficial, improvement-without-drugs being viewed as better than improvement-with-drugs. But if the patient's condition does not improve, then the outcome has neutral or negative value depending on the outcome expected had the drug regimen been followed.

Figure 5

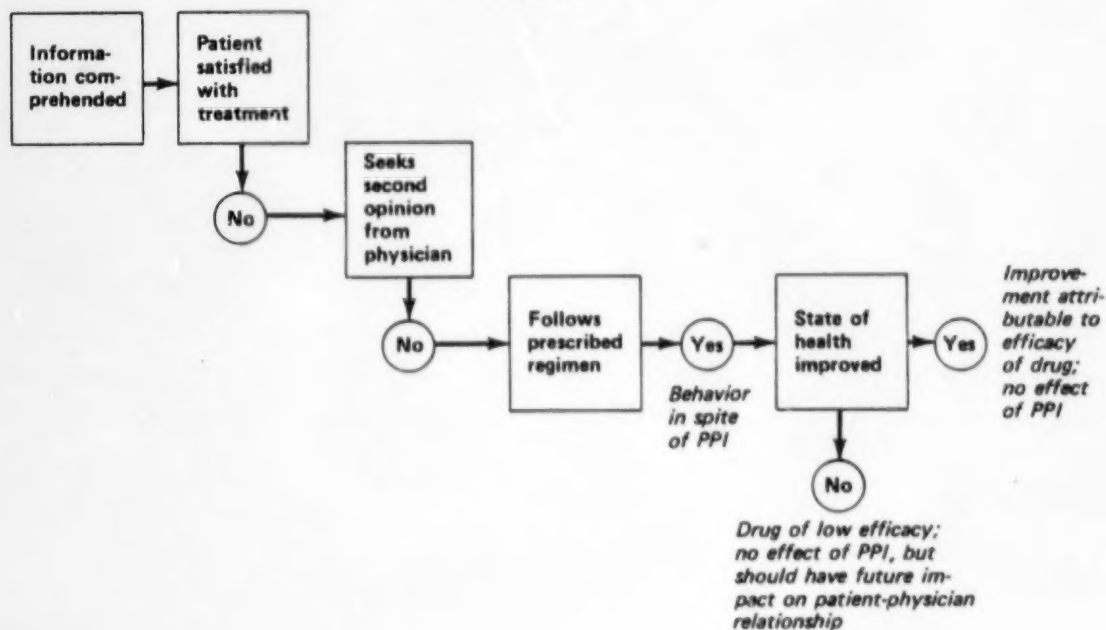
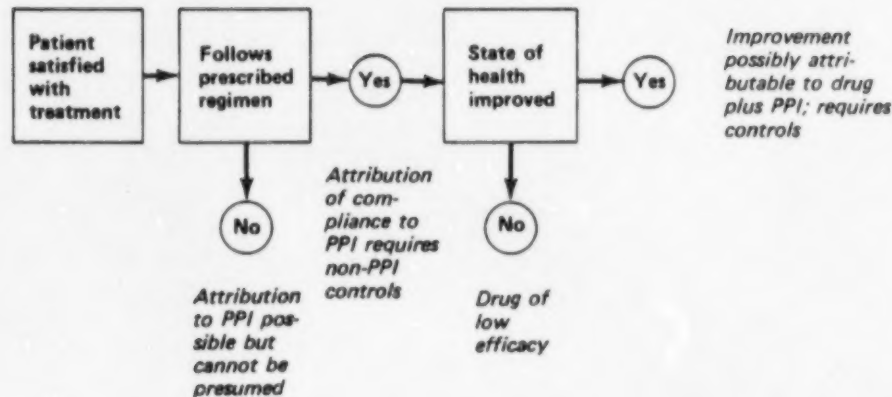


Figure 5 portrays outcomes which occur in spite of the PPI; the immediate consequences are drug-effects, not PPI-effects. But the PPI may have some longer-term consequence: the patient's trust in drugs, in PPI importance, in his or her physician, or in the medical enterprise may be influenced. But very few evaluations would discover these effects, since the time frame for their appearance may be longer than that of the evaluation.

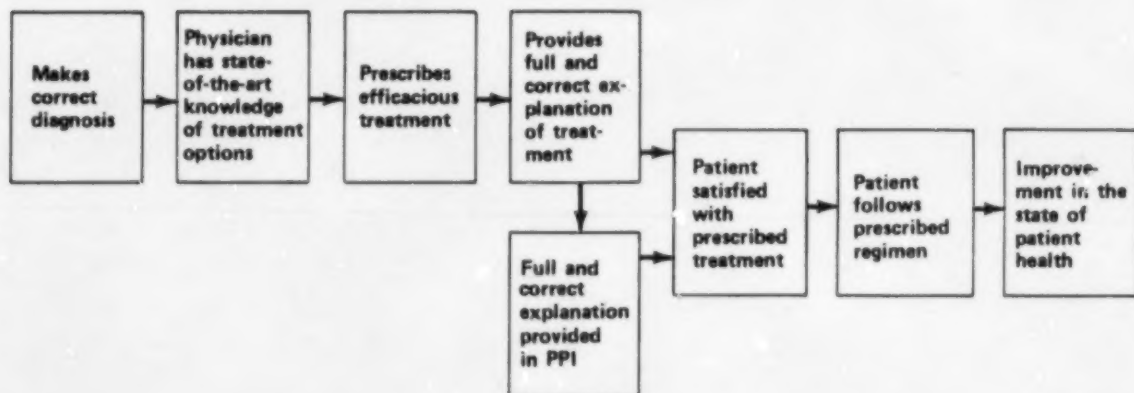
Figure 6



In Figure 6, none of the possible attributions are simple. Comparison or control groups are required to support any causal argument.

All of the examination thus far has focused on the behavior of the patient. But it has been hypothesized that the most important effects of Patient Package Inserts will be found in physician behavior, or alternatively, on physician-patient interaction. Using the approach already illustrated, Figure 7 presents the intended sequence which starts with the physician.

Figure 7
PHYSICIAN RATIONALE – INTENDED SEQUENCE



The complications will be examined very briefly with annotated figures carrying the explanatory burden. Figure 8 represents a plausible outcome which has nothing to do with PPIs. The same may be said of Figure 9.

PHYSICIAN RATIONALES – COMPLICATIONS

Figure 8

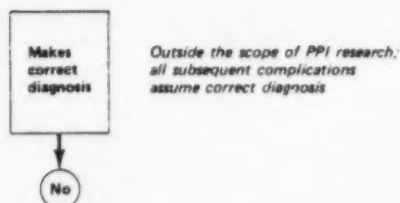


Figure 9

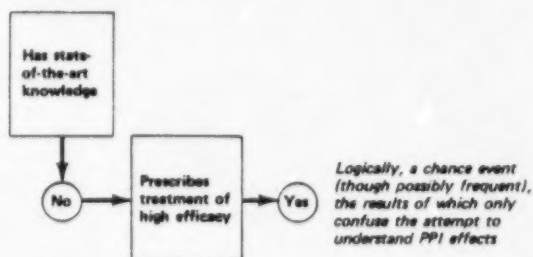


Figure 10 is the starting point for the sequences which involve the PPI. Figure 11 is the first such sequence; it is one in which PPI information leads to patient dissatisfaction with the prescribed treatment. Some of the possible consequences are shown and some could be attributed to PPIs by a careful evaluation.

Figure 10

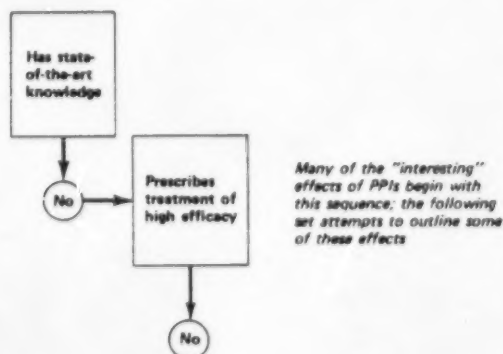


Figure 11

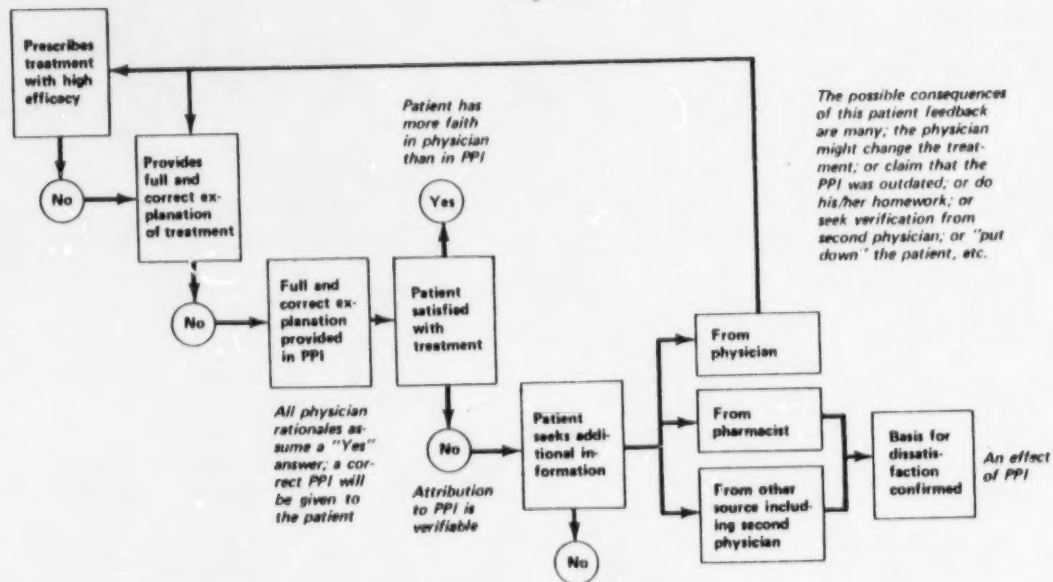


Figure 12 shows a quite different complication, one which might be *caused* by the PPI. The presumption is that the information presented impersonally by the PPI may be frightening, whereas the same information could be presented by the physician without alarming the patient.

Figure 12

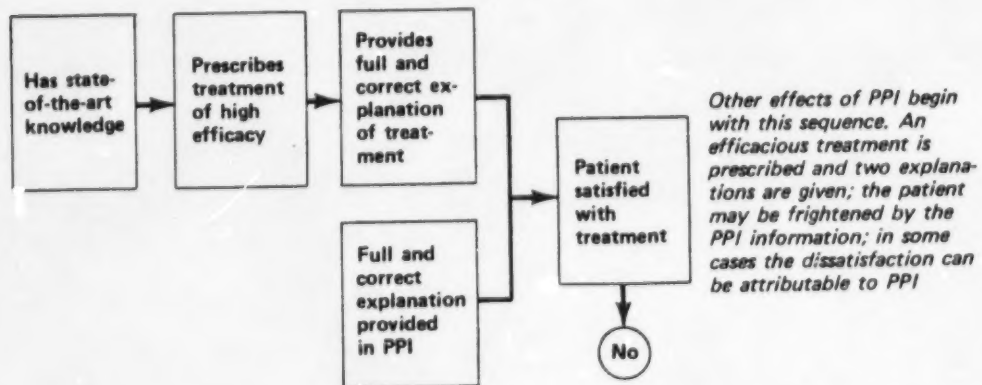
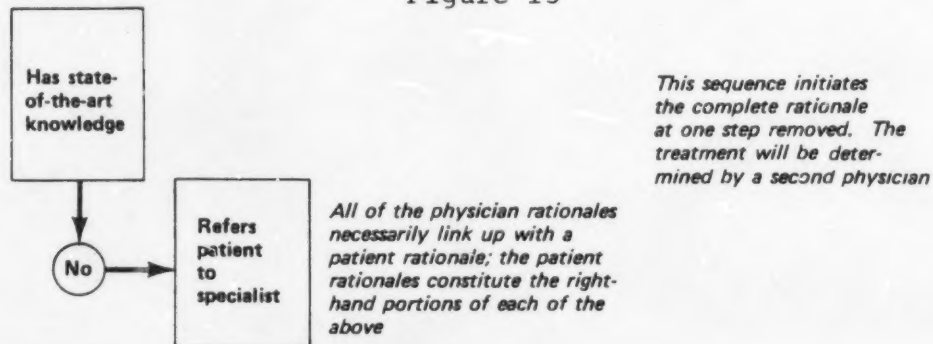


Figure 13 presents an hypothesized effect which is highly plausible and which, if it became a frequent occurrence, would increase the overall cost of medical services. The underlying rationale is that many practitioners will narrow the range of drugs which they are willing to prescribe. One might expect

some physicians in general practice to write fewer prescriptions for Valium and to refer more patients to psychiatrists, as one example.

Figure 13



The above examples are illustrative rather than exhaustive; the set of plausible outcomes is a large one. In similar fashion, one could prepare the intended sequences and complications for the pharmacist, the nurse, the pharmaceutical industry, the underwriters of malpractice insurance, or the consumer affairs agencies. All of these actors are included in the system which the PPI will enter and all are candidates for consideration by an evaluator. Some may be largely irrelevant and properly would be dropped after very brief exploration. But until such exploration has been done, they *are* candidates.

The Document Design Project has prepared broad-brush preliminary analyses of other public documents along these lines -- the IRS Form 1040 being one of the more widely known. We find the approach useful in several ways. First, it helps to identify and distinguish among pure document problems, mixed document-systems problems, and problems which are predominantly those of the system. A common result is an increased awareness that a document is often *not* the potent source of variance which some have expected it to be. The implication for evaluation seems evident. Second, the approach highlights the differing design requirements which accompany differing foci -- or differing definitions -- of the evaluation.. And third,

the approach provides an explicit and public mechanism for linking the objectives of an evaluation to the instruments and procedures to be used in meeting these objectives.

The approach is perfectly general. The implications which we derive from this brief examination of the Patient Package Insert differ only in detail from those which could be derived from examining any document in a real-world context. What are these implications?

First of all, there are multiple meanings of the verb "evaluate" and all meanings can be legitimate. It may be entirely appropriate to conduct a narrowly-focused study of one process, or one hypothesized effect. What seems to be important is to have some kind of map -- however crudely drawn -- of the overall activity, so that the small and apparently isolated study can be fitted into or at least understood as a part of a larger puzzle.

It follows, I believe, that purely descriptive studies are not only legitimate, but entirely necessary if one aspires to an overall, or "impact" assessment. I am not convinced that it is either necessary or possible to do experiments or quasi-experiments on important interventions in the real world. But even if we can and should somehow overcome the real-world's reluctance to serve as a laboratory, we should certainly precede the experiment with the careful descriptive work necessary to reveal what the experiment is to be about. Such work is seldom done.

The above can probably be subsumed by reverting to the "systems approach" battle cry of the 1950s. However outmoded, systems thinking is still required. We cannot treat an intervention, as described by the intervener, as all that has happened. We cannot even assume that any processes have taken place. We cannot measure some ultimate dependent variable and ascribe its level to the workings of the intervention.

We not only need to document what happens inside the black box, but we must measure also the workings of the material in which the black box is suspended.

Finally, I would like to call attention to our ignorance concerning time frames for the appearance or disappearance of expected effects. What is the effect over time of repeated warnings? Regarding the same drug or different drugs? How many call-backs from concerned patients are required to produce a change in physician prescribing behavior? What will be the cumulative effect of increased coverage by PPIs? The PPI for oral contraceptives was widely read; but it was the only drug given such attention. When ten or fifty or one hundred or *all* drugs are so treated, will the PPI be treated as warranties now are?* What about the generations born into a world where PPIs are standard accompaniments of prescription drugs? Will they read them?

Evaluation badly needs to become an historical undertaking. The one-shot study will never do.

* There is pressure on FDA to require PPIs to include a statement such as "the effect of this drug on the fetus, if taken during pregnancy by the mother, has not been adequately studied." The statement would presumably appear on PPIs for most drugs, as does the "Surgeon General's message" on all packages of cigarettes.